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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,306	09/25/2006	David Becker	US040173US	1780

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EXAMINER	
GUPTA, VANI	

ART UNIT	PAPER NUMBER
3777	

NOTIFICATION DATE	DELIVERY MODE
04/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/599,306	BECKER ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Declaration under 37 CFR 1.132 filed March 24, 2011 is insufficient to overcome the rejection of claims 1, 2, and 4 – 20 based upon the rejection as set forth in the last Office action because: the statements only refer to the intended use or purpose of the Magnusson reference and present invention, and does not thing to address the combined teachings of Silverstein and Magnusson that suggest the **obvious** need to provide the center of gravity at the handle portion of the handheld probe. Please refer to the rejections below for more details.

Applicant should note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the combination of the prior art teachings suggest that they are capable of performing the intended use, then they meet the claim.

Applicant should also note that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2 , 4 – 10, and 17 – 20 are rejected under 35 U.S.C. 103(b) as being unpatentable over Silverstein et al. (US 5,178,150) in view of Magnusson (US 4,007,735).

Regarding Claims 1 and 2, Silverstein et al. (hereinafter Silverstein) discloses an ultrasonic intracavity probe (**fig. 1**) for scanning a volumetric region from within the body comprising:

a handle section **(36)** to be held during the use of the probe (col. 4, ll. 58 – 60);

a shaft section **(32)** having a distal end **(12, 14, 34)**, which is to be inserted into a body cavity during use of the probe (col. 2, ll. 57, and 66 – 67; col. 4, ll. 40 and 47) and

a transducer disposed at the distal end **(fig. 2, 52)**, wherein an array ultrasound transducer, when rotated (col. 4, ll. 55 – 58) is capable of producing three-dimensional or volumetric images (col. 4, ll. 61 – 66) as is known in the ordinary of art.

More specifically, Silverstein also discloses that the transducer is pivotally movably mounted *("rotationally," "linearly," etc.* – col. 4, ll. 55 – 58) within the fluid chamber/balloon **(flexible bag, 62)**.

Figures 2 - 4 depict an arrangement of the transducer within the fluid-chamber-balloon combination. The liquid bath or acoustic coupling fluid **(64)** is within the fluid-chamber-flexible-bag located at the distal end of the shaft (col. 3, lines 14- 16) and therefore, is constrained to the shaft section to the exclusion of the handle section. According to **figs. 2 - 4**, a portion of the coupling fluid is located between the array transducer and the distal end of the shaft during scanning.

The pivotally mounted array transducer **(52)** is located also in a rigidly dimensioned compartment at the distal end of the shaft section **(fig. 4, (50) and (70))**, wherein the transducer body **(50)** and curved portion **(70)** make up the rigidly dimensioned compartment. As shown in fig. 4, the compartment is located at the distal end.

A motor comprising several parts is located in the handle section (col. 6, line 59 – col. 7, line 13) and is connected or coupled to the array transducer by a drive mechanism *("actuating* rod," col. 6, line 35 – 58) that moves or pivots or rotates the array transducer during scanning (col. 6, line 35 - col. 7, line 38).

The liquid bath, or "acoustic coupling fluid," **(64)** is contained within the area of the compartment and surrounds the transducer and the compartment. That is, at least a portion of the liquid bath is located between the array transducer and the distal end of the shaft during scanning (col. 5, ll. 49 – 63).

While Silverstein differs from Claim 1 in that Silverstein does not specifically suggest that the center of gravity of the probe is located in the handle section, it would have been obvious and well within the realm of ordinary skill in the art to provide the center of gravity, or the balance point, or most of the weight, at the handle portion for ease of use and/or optimal treatment results. As Magnusson explains, the center gravity of Magnusson's suggested medical probe is located at the handle section of the probe, where the motor is located, so that the generated energy is transmitted evenly through the shaft of the medical probe and provides optimal treatment results; and also so that the handling of the medical probe by the user is optimal (col. 2, ll. 19 – 23; and col. 3, ll. 36 – 63). Additionally, as it would be known in the art that center of gravity of the probe would be predicated by the dimensions, materials, position,

size, and weight of the components and the probe as a whole, modifying Silverstein to obtain a center of gravity in the handle would involve only routine skill in the art. For example, this would entail mere arrangement of parts, which does not receive any patentable weight because it would not produce any unexpected results. See In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

Regarding claims 4 – 10, Applicant should note that providing the transducer mount assembly having a proximal termination within one and one-half of the distal end of the shaft section; or providing a liquid bath wherein 90% of the liquid bath is contained within the transducer mount assembly; or providing a liquid bath wherein the liquid bath has a volume of "less than 25 cc of liquid," or "less than 10 cc of liquid," or "approximately 6 cc of liquid;" or providing a liquid bath wherein 90% of the liquid bath in the most distal 25% of the length of the shaft section involves only rearrangement of parts and does not receive any patentable weight since Applicant has not explained how the transducer mount assembly would perform differently or better than the prior art of record. Nonetheless, it would be obvious to one skilled in the art to provide on or more of the aforementioned arrangements so that one could provide optimal (smaller) size of the device for patient comfort; provide optimal deliverance of energy; and provide optimal acoustic coupling and impedance matching by the liquid, as suggested by Silverstein (col. 2, line 55 – col. 3, line 8).

Regarding Claims 17 – 19, Applicant should note that providing a probe with weight less than 400 grams, or less than 300 grams, or approximately 250 grams involves only routine skill in the art such as rescaling or changing size or proportion and does not establish patentability over prior art. See In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

Regarding claim 20, Silverstein suggests that components of the shaft of the intracavity probe are made with materials at least equal to the density of the stainless steel components of the drive mechanism (col. 5, ll. 55 – 58).

3. Claims 11 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein and Magnusson as applied to Claim 1 above, further in view of Bushek et al. (US 6,315,710).

Regarding claims 11 – 16, Silverstein in view of Magnusson suggests a transducer mount assembly, wherein the transducer array **(52)** is mounted to a transducer mount assembly having a main body and located in the distal end of the shaft section, which extends from the handle such that the transducer array is free to rotate or pivot about the axis of transducer region **(figs. 2 and 4, 50, 54, 58, 80**; col. 6, ll. 35 – 58).

Silverstein in view of Magnusson does not disclose specifically that the main body of the transducer mount assembly is formed of material lighter than stainless steel.

However, Bushek et al. teaches a hearing device, insertable into a cavity such as a ear, comprising a transducer mount assembly **(fig. 11, 220)** formed from a material other than stainless steel such as polycarbonate, silicone, titanium, etc. (col. 13, lines 60 – 67). Bushek et al. also teaches a mount assembly that allows the rotation and delicate positioning of the transducer (col. 13, lines 31 – 35 and 52 – 59).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Silverstein and Magnusson, and Bushek before one at the time the invention was made, to modify the ultrasonic probe teachings of Silverstein and Magnusson with transducer

assembly materials teachings of Bushek so that one could provide optimal positioning of the transducer mount assembly.

With further respect to Claim 12, Silverstein suggests in **Fig. 4** that transducer mount assembly portion **(50)** provides a transducer cradle, which supports transducer array (**52**).

With further respect to claims 13 and 14, transducer cradle includes a solid body **(70)** located behind array transducer which displaces volume of coupling fluid; it is shaped so that it passes more easily through the liquid bath (**Fig. 4**).

With further respect to claims 15 and 16, Silverstein teaches that the transducer mount assembly includes wear surfaces **(Fig. 4, #80, 120, 122)**, wherein wear surfaces are part of the drive mechanism (col. 6, ll. 40 – 45; and col. 7, ll. 22 – 25); and teaches that the transducer mount assembly may be formed of materials such as stainless steel (col. 7, ll. 3 and 20).

Response to Arguments

4. Applicant's arguments filed March 24, 2011 have been fully considered but they are not persuasive.

In response to applicant's argument that US Pat. 4,007,735 (Magnusson) is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Magnusson provides a medical-based intracavity handheld probe that provides teachings for the need to place the center of gravity in the handle section of the probe. Applicant should also note that "in a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to

permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist." See also In re Bigio, 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004)

Furthermore, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known **at the time of the invention**, and on what such a person would have **reasonably expected to have been able to do in view of that knowledge**. This is so regardless of whether the source of that knowledge and ability was **documentary prior art, general knowledge in the art, or common sense**." – MPEP 2141 (section II last paragraph). In view of common sense, "**A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton**." KSR, 550 U.S. at ___, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. at ___, 82 USPQ2d at 1396. In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Federal Circuit has stated that examiners and administrative patent judges on the Board are "persons of scientific competence in the fields in which they work" and that their findings are "informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art." In re Berg , 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).

Applicant argues also on pp. 5 – 6 that the compliant bag **(62)** of Silverstein et al. does not comprise a "rigidly dimensioned compartment," and therefore Silverstein et al. does not

teach this feature of Claim 1. Examiner respectfully disagrees and points out that the distal end comprises, **aside from the compliant bag to which the Applicant refers to,** components that make up the rigidly dimensioned compartment (for emphasis)**.** If the Applicant carefully reads the aforementioned rejection above, Applicant will see that the elongating bag is just that, a bag **(62)**. The rigidly dimensioned component is an entirely different component **(50)**. Please see **figs. 2 and 4**, and the above rejection for more details.

Applicant argues also on p. 6 that US pat. 6,315,710 (Bushek et al.) is non-analogous art. Examiner respectfully disagrees. As indicated in the rejection(s), Bushek et al. teaches useable materials other than stainless steel for components that must fit within a small intrabody cavity. Applicant has not claimed that the intracavity probe of the present invention is for a specific intracavity of a patient's body (i.e., not the ear), nor has Applicant indicated any unsolved problem or unexpected results by using Bushek et al. Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Please refer also to above response with respect Magnusson teachings for details on combing "non-analogous art" and common-sense analysis.

Conclusion

5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777